Applicant: Garrity et al. Serial No.: 09/761,969 Filed: January 16, 2001

Page 12 of 14

Remarks

Claims 1-84 were pending. By way of this response, claims 44-65 have been cancelled, and claims 3, 4, 37, 66, 67, 70, 71, 75, 77, 79, 80, 81, 83, and 84 have been amended. Support for the amendments to the specification and the claims can be found in the application as originally filed, and no new matter has been added. Accordingly, claims 1-43 and 66-84 are currently pending.

The Office Action states that restriction to one allegedly distinct invention is required under 35 U.S.C. § 121.

Applicant hereby elects Group I (claims 1-41) drawn a kit for determining vitamin D concentration, as identified in the Office Action.

In addition, Applicant respectfully submits that in view of the amendments to the claims herein and the remarks hereinbelow, that claims 1-43, and 66-84 define a single invention, and Applicant respectfully requests that claims 1-43 and 66-84 be examined on the merits.

The two criteria for a proper requirement for restriction between patentably distinct inventions are: (A) The inventions must be independent (see MPEP § 802.01, § 806.04, § 808.01) or distinct as claimed (see MPEP § 806.05 - § 806.05(i)); (and (B) There must be a serious burden on the examiner if restriction is required (see MPEP § 803.02, § 806.04(a) - § 806.04(i), § 808.01(a), and § 808.02) (see MPEP § 803).

Regarding inventions I and II (claims 1-41, and 42-43, respectively), Applicant respectfully submits that there is no serious burden on the Examiner in examining claims 1-41 and 42-43 because, as indicated in the Office Action, the claims are classified in the same class (i.e., class 422, subclass 61). Because the Office Action has not met the two requirements identified above to establish a proper restriction requirement, Applicant submits that restriction between Group I and II is improper. Applicant respectfully requests that claims 1-43 be examined together.

Applicant: Garrity et al. Serial No.: 09/761,969 Filed: January 16, 2001

Page 13 of 14

Regarding inventions V, VI, and VII (claims 66-79, 80-83, and 84, respectively), Applicant has amended claims 66, 80, and 84, as set forth above. In view of the amendments to the claims, Applicant respectfully submits that claims 66-84 are directed to a single invention. As indicated in the Office Action, inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects. In the present case, the methods of claims 66-84 are disclosed as being capable of being used together. The methods of claims 80-84 can be used with the method of claim 66 to determine the concentration of a vitamin D component in a biological sample. Thus, because the methods of claims 66-84 can be used together) claims 66-84 are related.

Regarding inventions V, VI, and VII and I and II, Applicant respectfully submits that in view of the amendments to the claims, the claims are not patentably distinct. Applicant respectfully submits that each of the independent method claims require the claimed methods to be performed using a holder or tube. Holders or tubes are provided in assay kits. Thus, because the claimed methods require a tube or holder, Applicant submits that the claimed methods cannot be practiced by another materially different apparatus or by hand, and thus restriction between inventions V, VI, and VII, and I and II is improper.

Accordingly, because inventions I and II are related, because inventions V, VI, and VII are related, and because inventions V, VI, and VII are not distinct from inventions I and II, Applicant respectfully submits that restriction of inventions I, II, V, VI, and VII be withdrawn, and that examination proceed with respect to the currently pending claims (i.e., claims 1-43 and 66-84).

9494501764

Applicant: Garrity et al. Serial No.: 09/761,969 Filed: January 16, 2001

Page 14 of 14

If a telephone interview would be of assistance in advancing prosecution of the subject application, Applicant's undersigned representative invites the Examiner to telephone him at the number provided below.

Date: 5/6/03

Respectfully submitted,

Greg S. Hollrigel

Registration No. 45,374

Stout, Uxa, Buyan & Mullins, LLP

4 Venture, Suite 300 Irvine, California 92618

Telephone: 949-450-1750 Facsimile: 949-450-1764